Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
Approved for use through xx/xx/200x. OMB 0651-00xx
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 117163.00087

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/652,861	08/29/2003

First Named Inventor: Ulrich BUSCH et al.

Art Unit	Examiner
3762	Christopher A. FLORY

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

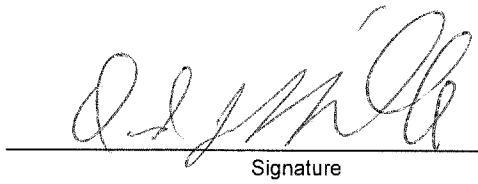
I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 50,914.

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____



Signature

David J. Muzilla
Typed or printed name

(330) 864-5550
Telephone number

6-25-07
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Busch, et al.	**Examiner:**	**Flory, C. A.**
Serial No.:	10/652,861	**Art Unit:**	3762
Filed:	29 August 2003	**Date:**	25 June 2007

For: A BIATRIAL TRIPLE-CHAMBER CARDIAC PACEMAKER WITH MULTI-CONDITIONAL INHIBITION OF SECOND ATRIAL STIMULATION

ARGUMENTS ACCOMPANYING PRE-APPEAL BRIEF REQUEST FOR REVIEW

Claims 1-16 were pending in the case at the time of the Final Office Action. Claims 1-16 are currently pending in the application. In the Final Office Action, Limousin (US 5,514,161), hereinafter Limousin, is used to reject the independent claims 1 and 2, as well as other claims, as being unpatentable under 35 U.S.C. 103(a). Applicants will focus on the independent claims 1 and 2 for the purposes of the arguments presented herein. Independent claims 1 and 2 are listed below (with emphasis added):

Claim 1 (previously presented): A biatrial triple-chamber pacemaker for use with a heart having a first and a second atrium and a first and a second ventricle, said pacemaker comprising:

at least one sensing unit for sense events of the first atrium and the first ventricle;

at least one stimulation unit which is adapted to produce stimulation pulses to the second atrium and the first ventricle; and

a control unit which is connected to the sensing unit and the stimulation unit and which is adapted to evaluate, for actuating the stimulation unit, at least the atrial sense events (A_R-Sense) associated with the first atrium and the ventricular sense events (V-Sense) associated with the first ventricle;

wherein the stimulation unit is actuated with regard to a ventricular escape interval and a postatrial ventricular blanking time such that an occurrence of the atrial sense event (A_R-Sense) triggers the ventricular escape interval, at the end of which a ventricular stimulation pulse is triggered <u>if same is not inhibited by an occurrence of the ventricular sense event within the ventricular escape interval and outside the postatrial ventricular blanking time,</u>

wherein the stimulation unit is actuated with regard to an interatrial conduction time such that <u>an occurrence of the atrial sense event (A_R-Sense) triggers the interatrial conduction time, at the end of which a stimulation pulse to the second atrium is triggered</u> if the stimulation pulse to the second atrium is not inhibited, and

wherein the stimulation unit is actuated such that the delivery of a stimulation pulse to the second atrium is suppressed when previously an occurrence of the ventricular sense event occurs in a crosstalk window which adjoins a postatrial ventricular blanking time and at the same time a time interval, between a last ventricular sensed event occurring outside the crosstalk window and a next possible (scheduled) ventricular stimulation event, is greater than a predetermined maximum value.

Claim 2 (previously presented): A biatrial triple-chamber cardiac pacemaker for use with a heart having a first and a second atrium and a first and a second ventricle, said pacemaker comprising:

at least one sensing unit for sense events of the first atrium and the first ventricle;

at least one stimulation unit which is adapted to produce stimulation pulses to the second atrium and the first ventricle; and

a control unit which is connected to the sensing unit and the stimulation unit and which is adapted to evaluate, for actuating the stimulation unit, at least the atrial sense events (A_R-Sense) associated with the first atrium and the ventricular sense events (V-Sense) associated with the first ventricle;

wherein the stimulation unit is actuated with regard to a ventricular escape interval and a postatrial ventricular blanking time such that an occurrence of the atrial sense event (A_R-Sense) triggers the ventricular escape interval, at the end of which a ventricular stimulation pulse is triggered if same is not inhibited by an occurrence of the a ventricular sense event within the ventricular escape interval and outside the postatrial ventricular blanking time;

wherein the stimulation unit is actuated with regard to an interatrial conduction time such that an occurrence of the atrial sense event (A_R-Sense) triggers the interatrial conduction time, at the end of which a stimulation pulse to the second atrium is triggered if the stimulation pulse to the second atrium is not inhibited; and

wherein the stimulation unit is actuated such that the delivery of a stimulation pulse to the second atrium is suppressed when a ventricular sense event occurs during an upper tracking interval operating mode in which the cardiac pacemaker works at a predetermined maximum stimulation rate.

Errors in Facts and Omission or Presence of Essential Elements

In the outstanding Office action, the Examiner takes the position that Limousin teaches the claimed invention of claims 1 and 2, or that certain elements of claims 1 and 2 would have been obvious to one skilled in the art. The various specific positions taken by the Examiner in the outstanding Office action appear to be errors in fact, and are discussed below herein.

The figure below characterizes the conditions under which the stimulation unit is actuated in accordance with independent claims 1 and 2 of the present application. Referring to the figure

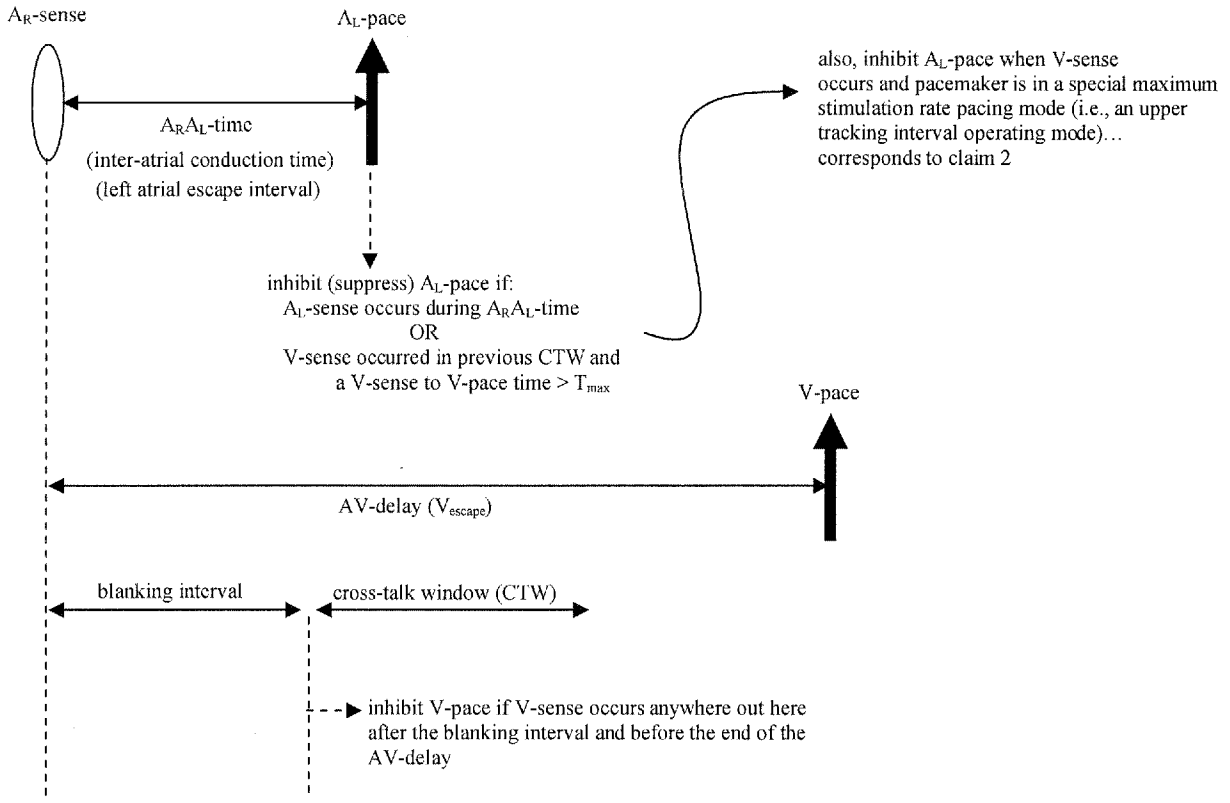
below, the occurrence of a right atrial sense event (A_R-sense) triggers an inter-atrial conduction time (also known as a A_RA_L-time or a left atrial escape interval) which is an artificial time controlled by a timer (not a natural A_RA_L-time). The occurrence of a right atrial sense event (A_R-sense) also triggers a ventricular escape interval V_{escape} (AV-delay) including a blanking interval followed by a cross-talk window (CTW) time.

At the end of the A_RA_L-time, a stimulation pulse A_L-pace to the second atrium (left atrium) is triggered unless inhibited. A_L-pace may be inhibited if a left atrial sense event (A_L-sense) occurs during the A_RA_L-time, or if a ventrical sense event (V-sense) occurred in the previous CTW and, at the same time, a time interval (V-sense to V-pace) between a last ventricular sensed event occurring outside the CTW and a next possible (scheduled) ventricular stimulation event (V-pace) is greater than a predetermined maximum value (T_{max}). Also, if the pacemaker of the present invention is in a special maximum stimulation rate pacing mode (i.e., an upper tracking interval operating mode), then A_L-pace will be inhibited when a V-sense occurs. Furthermore, a ventricular stimulation pulse (V-pace) will occur at the end of V_{escape} unless there was the occurrence of a ventricular sense event (V-sense) within the V_{escape} interval but outside of the blanking interval. Such limitations of claims 1 and 2 of the present application are not taught or suggested by Limousin, and are certainly not obvious in light of the complexity to these actuating conditions of the stimulation unit.

In contrast to claims 1 and 2 of the present application, Limousin describes (see column 5 lines 39-67 to column 6 lines 1-16) an atrial circuit that senses and measures the interval between two successive sensed atrial signals. An evaluation is made of the diminution or rate of diminution of that time interval and is compared to a predetermined limit value. If the limit value is not exceeded, the situation is considered normal and an atrial stimulation is immediately provided to both atria. If the limit value is exceeded, a "window of listening" is opened on the ventricular electrode. If a signal is sensed on the ventricular electrode during the listening window, no atrial stimulation is provided. If no signal is sensed, the atrium is then stimulated at the end of the listening window. Such operation of Limousin is clearly quite different than that of claims 1 and 2 of the present application with respect to actuating a stimulation unit as described above. Any equivalence of Limousin to claims 1 and 2, with respect to the conditions

under which a stimulation unit is actuated, as suggested by the Examiner in the outstanding Office action are errors in fact. Furthermore, Limousin seems to require that both atria (right and left) be stimulated at the same time. Such simultaneous stimulation of atria would seem to prevent the proper operation of the pacemaker of claims 1 and 2 of the present application.

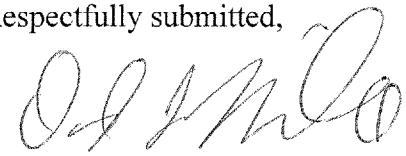
With respect to the 35 U.S.C. 112 rejections of the outstanding Office action, the interatrial conduction time (A_RA_L-time) is an artificially controlled time which is intiated by A_R-sense as described above and, therefore, has nothing to do with more than one sensing unit being present. The one sensing unit (e.g., the A_R sensing unit) and one stimulation unit (e.g., the A_L stimulation unit) are all that are relevant with respect to the A_RA_L-time for claims 1 and claims 2 of the present invention. Furthermore, it should be noted that, by means of a switch, a single atrial sensing unit and a single atrial stimulation unit could theoretically be used for independently sensing atrial events in the right and the left atrium and for generating right and left atrial stimulation pulses by means of the switch.



Therefore, in view of at least the foregoing, it is respectfully submitted that independent claim 1 and independent claim 2 are not unpatentable over Limousin, and it is respectfully submitted that independent claim 1 and independent claim 2 each define allowable subject matter. Also, since claims 3-16 depend either directly or indirectly from claim 1 or claim 2, it is respectfully submitted that claims 3-16 define allowable subject matter as well. Applicants respectfully request that the rejection of claims 1-16 under 35 U.S.C. 103(a) be removed and that the rejections of claims 1-2 under 35 U.S.C. 112 be removed.

Accordingly, the applicant respectfully requests reconsideration of the rejections and objections based on at least the foregoing. After such reconsideration, it is urged that allowance of claims 1-16 will be in order.

Respectfully submitted,



David J. Muzilla
Registration No. 50,914

Hahn Loeser & Parks LLP
One GOJO Plaza
Suite 300
Akron, OH 44311-1076
(330) 864-5550
Fax 330-864-7986
djmuzilla@hahnlaw.com

CUSTOMER No. 021324